UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

ETHEL KELLOGG, Plaintiff, v. WYETH, Individually and as Successor-in-Interest to A.H. ROBINS COMPANY, INC. and AMERICAN HOME PRODUCTS CORPORATION; SCHWARZ PHARMA, INC.; ACTAVIS, INC.; ACTAVIS-ELIZABETH, L.L.C.; ALPHARMA, INC.; PUREPAC PHARMACEUTICAL COMPANY, INC.; TEVA PHARMACEUTICALS, USA, INC.; BAR PHARMACEUTICALS, INC.; PLIVA, INC.; and DRUG COMPANY DOES 1 THROUGH 10, inclusive, Defendants.	:	Case No. 2:07-cv-82

MEMORANDUM OPINION and ORDER

Generic drug manufacturer defendants Actavis-Elizabeth, L.L.C. (“Actavis”), Teva Pharmaceuticals, USA, Inc. (“Teva”), Barr Pharmaceuticals, LLC (“Barr”), and Pliva, Inc. (“Pliva”) have moved for an amendment of this Court’s December 17, 2008 Opinion and Order certifying it for immediate appeal, pursuant to 28 U.S.C. § 1292(b). The moving parties have also requested a stay of the proceedings pending resolution of an appeal. Defendant Wyeth, Inc. (“Wyeth”) takes no position on an interlocutory appeal, but urges a stay of all proceedings against all defendants, should the Court permit an interlocutory appeal. Plaintiff Ethel Kellogg opposes the motion. For the reasons that

follow, the motion (Doc. 109) is **denied.**[1]

Kellogg's second amended complaint alleges that Wyeth, maker of Reglan, and generic drug manufacturers Actavis, Teva, Barr and Pliva, among others, are liable for her overexposure to metoclopramide because they were aware of the risk of long-term use of the drug, yet took no steps to discourage the practice. The generic drug manufacturer defendants variously moved to dismiss the complaint for failure to state a claim under Rule 12(b)(6), for judgment on the pleadings or for summary judgment, arguing that because federal law required them to label their product identically to the brand name drug, federal law preempted any state law tort claim based on failure-to-warn. In an Opinion and Order dated December 17, 2008, this Court denied the motions, concluding that "[a]pplying the presumption against preemption, the generic drug manufacturer defendants have not shown that Congress clearly intended to preempt all failure-to-warn litigation by requiring that ANDA applicants label their drugs identically to the reference listed drug." (Op. & Order 33.)

On February 9, 2009 the generic drug manufacturer defendants filed their request for an amended order permitting an immediate appeal under § 1292(b). On March 4, 2009, the United States Supreme Court issued its decision in *Wyeth v. Levine*, 129 S. Ct.

[1] Pursuant to Local Rule 7.1(a)(6), the Court declines to hear argument on the motion, finding that the issues are thoroughly addressed by the parties' submissions.

1187 (2009), which held that state law failure-to-warn claims against the brand name manufacturer of an anti-nausea medication are not preempted by federal law. *Id.* at 1204. Anticipating the argument that appellate review might be mooted by the Supreme Court's decision, the generic manufacturers assert that the issue in this case differs from the issue decided in *Levine*, and that the decision actually supports preemption of tort claims against generic drug manufacturers.

Section 1292(b) of Title 28 United States Code provides that when a district judge believes that an otherwise nonappealable order in a civil action "involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation," he may certify the order for an immediate appeal. 28 U.S.C. § 1292(b); *see Casey v. Long Island R. Co.*, 406 F.3d 142, 146 (2d Cir. 2005). Section 1292(b) "is a rare exception to the final judgment rule," and its "use . . . is reserved for those cases where an intermediate appeal may avoid protracted litigation." *Koehler v. Bank of Bermuda Ltd.*, 101 F.3d 863, 865-66 (2d Cir. 1996).

This is not such a case. Although this Court's ruling does involve a controlling question of law, the recent *Levine* decision reduces substantially the grounds for difference of opinion

concerning whether federal law preempts state law failure-to-warn cases against drug manufacturers. Moreover, it is not at all clear that an immediate appeal might advance the ultimate termination of this litigation.

The generic drug manufacturer defendants point out that because *Levine* involved a branded drug, not a generic drug, the preemption question as applied to generic manufacturers was not before the Supreme Court and was not decided by it. This is of course true. The defendants argue that the "changes being effected" or "CBE" provision discussed in *Levine* does not apply to generic manufacturers, and that they are prohibited from changing their label to add or strengthen a warning absent FDA approval. Had the Supreme Court issued the sort of opinion that merely narrowly parsed the terms and applicability of the CBE provision to brand name manufacturers, their point would carry more weight. That is not what the Supreme Court did, however.

Justice Stevens, writing for the majority, prefaced the discussion of Wyeth's preemption arguments by identifying two key facts decided at trial and two guiding legal principles, and reviewing the history of "the controlling federal statute," the Federal Food, Drug, and Cosmetic Act ("FDCA") as amended. *Levine*, 129 S. Ct. at 1194. The facts were, one, that the jury determined that an inadequate warning was both a but-for and proximate cause of Levine's injury, and two, that the critical

defect in the drug's label was an inadequate warning about the risks of a particular form of administration. *Id.* Thus, it was unnecessary to decide whether a state law requiring a particular warning or banning a particular usage of the drug would be preempted. *Id.* Implicit was the acknowledgment that the availability of a full record and factual findings assisted the Court in framing the precise preemption question before it.

The two guiding legal principles were, one, that "'the purpose of Congress is the ultimate touchstone in every pre-emption case,'" and, two, that "'in all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.* at 1194-95 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)) (ellipses omitted).

To identify the "purpose of Congress," the Court reviewed the history of drugs and drug labeling, beginning in 1906. It discussed the provisions for premarket approval of new drugs. It highlighted the fact that the Drug Amendments of 1962 shifted the burden of proof on a drug's safety to the manufacturer and also required the manufacturer to prove the drug's effectiveness, by demonstrating that the drug was safe and effective under the

conditions "'prescribed, recommended, or suggested in the proposed labeling.'" *Id.* at 1195 (quoting § 102(d)). Congress took care at that time to preserve state law with a saving clause, and state common-law suits "'continued unabated.'" *Id.* at 1196 (quoting *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1017 (2008) (Ginsburg, J., dissenting)). The Court noted that as recently as 2007, when Congress granted the FDA the statutory authority to require a manufacturer to change its drug label based on newly acquired safety information, it did not require FDA preapproval of all changes to drug labels. *Id.* The Court concluded its review by stressing that the 2007 amendments to the FDCA continued to make clear that manufacturers remain responsible for updating their labels. *Id.*

Within this framework the Supreme Court addressed Wyeth's arguments that it is impossible for it to comply with both the state-law duties underlying Levine's claims and its federal labeling duties, and that requiring it to comply with a state-law duty to provide a stronger warning would obstruct the purposes and objectives of federal labeling regulation. It rejected both. It found that the CBE regulation permits a manufacturer to make a labeling change to add or strengthen a warning without waiting for FDA approval. *Id.* With polite skepticism it declined to accept the argument that strengthening a warning would render Wyeth vulnerable to charges of unauthorized distribution and

misbranding. *Id.* at 1197. The Court advised that "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." *Id.* at 1197-98.

The Court found no merit in Wyeth's argument that a state law duty to warn would frustrate the purposes and objectives of federal drug labeling regulation, noting the seventy-year history of coexistence between the FDCA and state common law suits. It decisively rejected the recent agency assertion that such suits would threaten FDA's role as the expert agency responsible for evaluating and regulating drugs as undeserving of any deference whatsoever. *Id.* at 1200-1201.

The Court concluded:

> In short, Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling. Congress has repeatedly declined to pre-empt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight. Although we recognize that some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case.

Id. at 1204.

What remains of the generic manufacturers' preemption arguments post-*Levine*? The generic manufacturers argue that they are bound by an entirely different set of rules. They must follow the label of the name brand manufacturer, they say, and only FDA may determine whether generic drug labeling should be

revised. They contend that the issue is not whether the FDCA preempts Kellogg's claims, but whether the Hatch-Waxman Amendments to the FDCA preempt her claims.

To be sure, one primary purpose of the Hatch-Waxman Amendments was to facilitate the availability of lower cost generic drugs. But the Hatch-Waxman Amendments to the FDCA were enacted in 1984, against the backdrop of decades of federal drug labeling regulation coexisting with state tort litigation. Only eight years earlier, Congress enacted an express preemption provision for medical devices. *See* Medical Device Amendments of 1976, Pub. L. 94-295, § 521, 90 Stat. 539, 574 (codified at 21 U.S.C. § 360k(a)). As the Supreme Court declared:

> [D]espite its 1976 enactment of an express pre-emption provision for medical devices, Congress has not enacted such a provision for prescription drugs. Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness. As Justice O'Connor explained in her opinion for a unanimous Court: "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989).

Levine, 129 S. Ct. at 1200 (citations omitted).

Given that Congress could and did insert an express preemption provision when it amended the FDCA in 1976 to provide for the safety and effectiveness of medical devices, it is

telling that Congress did not make any express preemption provision when it amended the FDCA in 1984 to authorize abbreviated new drug applications. Evidently, in the Congressional view, creating a streamlined process for generic drugs to reach the market did not preclude their manufacturers' duty to ensure the safety and effectiveness of their products.

FDA's own regulations bear this out. As this Court wrote in its earlier opinion, 21 C.F.R. § 314.97 requires an ANDA applicant to comply with the requirements of §§ 314.70 and 314.71 for NDAs. (Op. & Order 8.) Section 314.70 includes the CBE provisions. *See* 21 C.F.R. § 314.70(c)(6). The plain language of FDA's regulations communicates the obligation borne by name brand and generic manufacturers alike to revise a label to add or strengthen a warning in the light of newly acquired information. *See id.* § 314.70(c)(6)(iii)(A). This makes sense in light of the fact that brand name manufacturers may elect to manufacture and distribute a generic version of their own brand name drug--as Wyeth has done with Reglan--once the brand name drug loses patent protection. According to the defendants' logic, the same company that would have a duty to strengthen a warning or add a contraindication to its label as an NDA holder could argue that as a manufacturer of the generic form it escaped that same duty.

Thus, although the *Levine* decision did not definitively dispose of the issues in this case, its statement that

"[f]ailure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times," *Levine*, 129 S. Ct. at 1202, does not appear to permit the caveat, "except for generic drug manufacturers." *See Stacel v. Teva Pharms., USA*, No. 08 C 1143, 2009 WL 703274 at *6 (N.D. Ill. Mar. 16, 2009) (post-*Levine*, finding no preemption of state-law claims against generic drug manufacturer); *Schrock v. Wyeth, Inc.*, ___ F. Supp. 2d ___, ___, No. CIV-08-453-M, 2009 WL 635415 at *3 (W.D. Okla. Mar. 11, 2009) (same).

The generic manufacturer defendants contend that Justice Breyer's warning that a different FDA regulation might well have a preemptive effect points directly to this case. *See Levine*, 129 S. Ct. at 1204 (Breyer, J. concurring). This Court disagrees. Although he did allude to arguments some have made that state tort law can drive up the price of drugs, Justice Breyer stressed that should "[t]he FDA seek to determine whether and when state tort law acts as a help or a hindrance to achieving the safe drug-related medical care that Congress sought[, i]t may seek to embody those determinations in lawful specific regulations describing, for example, when labeling requirements serve as a ceiling as well as a floor." *Id.* (citations omitted). This does not come close to a hint that an unofficial FDA interpretation at odds with the plain language of

a regulation will have preemptive effect. Regardless, however, of whether Justice Breyer's remarks may be directed at state tort claims against generic drug manufacturers, certification in this case is inappropriate.

Certification of this Court's decision is not likely to advance materially the termination of this litigation for two reasons. One, Kellogg asserts claims of breach of express and implied warranties against the generic manufacturers that are not based on failure to provide adequate warnings of the risks of long-term use of metoclopramide. These claims would survive a Second Circuit decision that her failure-to-warn claims were preempted. Two, Wyeth remains a defendant in this case, and may or may not be affected by a decision that claims against generic manufacturers are preempted.[2] Kellogg's additional claims against Wyeth, of negligent and/or fraudulent misrepresentation would also survive a post-*Levine* preemption decision.

For the reasons stated above, the generic drug manufacturers' Motion for Amendment of Order to Include Statement Certifying an Interlocutory Appeal and Stay of Proceedings (Doc. 109) is **denied.**

[2] Wyeth asserts that Kellogg never ingested Reglan, but did ingest generic metoclopramide manufactured and distributed by Wyeth.

Dated at Burlington, in the District of Vermont, this 10th day of April, 2009.

/s/ William K. Sessions III
William K. Sessions III, Chief Judge
United States District Court